510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
#K042175

B. Purpose for Submission:
Device modification (Special 510k)

C. Analyte:
Heparin

D. Type of Test:
Quantitative

E. Applicant:
Medtronic Perfusion Systems

F. Proprietary and Established Names:
Medtronic CLOTtrac® HTC Coagulation Control; Coagulation Control Plasma

G. Regulatory Information:

1. Regulation section:
   864.5425 – Multipurpose System for in vitro Coagulation Studies
2. Classification:
   Class II
3. Product Code:
   GGN; JBP
4. Panel:
   Hematology (81)

H. Intended Use:

1. Intended use(s):
   The Medtronic CLOTtrac® HTC Coagulation Control is for in vitro diagnostic use to verify performance of the ACT instrument and Heparinase HR-HTC cartridges.
2. Indication(s) for use:
   Same as the Intended Use.
3. Special condition for use statement(s):
   N/A
4. Special instrument Requirements:
   Activated Clot Timer (ACT) instrumentation.

I. Device Description:

The CLOTtrac® HTC Coagulation Control is being modified to replace USP bovine heparin with USP porcine heparin. It consists of citrated sheep plasma, and stabilized sheep erythrocytes that are lyophilized and heparinized with USP porcine heparin. It is reconstituted to 6 U/ml with reagent grade water, and used as a fresh whole blood sample.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Medtronic, Inc. (HemoTec, Inc.) CLOTtrac® Heparinase Control
2. Predicate K number(s):
   #K902081
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	To verify performance of the CLOTtrac® Heparinase Cartridge and ACT instrument	Same
Instrumentation	Automated Coagulation Timer (ACT)	Same
Heparin concentration	6 Units/mL	Same
Stability (reconstituted)	2 hours at 15º-25º C.	Same
Expected results in channel clot time	90 – 150 seconds	Same
Storage (type and temperature)	Lyophilized; 2º-10º C.	Same
Differences		
Item	**Device**	**Predicate**
Heparin type	Porcine	Bovine

K. Standard/Guidance Document Referenced (if applicable):

ISO14971 – Medical Devices-Application of Risk Management to Medical Devices.

L. Test Principle:

The ACT instrument utilizes HR-HTC cartridges to generate an activated clotting time (ACT) in response to the heparin concentration in a whole blood sample. The

CLOTtrac® HTC Coagulation Control is designed to verify Channels 1 and 2 of the test cartridges.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. *Precision/Reproducibility:*
    Three lots of control were used to test cartridges (N=59) on the ACT instrument. Mean clot times for each lot, in Channel 1, were 106, 111 and 111 seconds, respectively. Within-lot precision, for each lot, was 3.4%, 4.2% and 4.1 % CV, respectively.

    Channel 2 generated expected clot times of > 999 seconds; except for 8% of controls that generated clot times of < 999 seconds.

    b. *Linearity/assay reportable range:*
    N/A
    c. *Traceability (controls, calibrators, or method):*
    The activated clotting time (ACT) method.
    d. *Detection limit:*
    N/A
    e. *Analytical specificity:*
    N/A
    f. *Assay cut-off:*
    N/A

2. Comparison studies:
    a. *Method comparison with predicate device:*
    N/A
    b. *Matrix comparison:*
    N/A

3. Clinical studies:
    a. *Clinical sensitivity:*
    N/A
    b. *Clinical specificity:*
    N/A
    c. *Other clinical supportive data (when a and b are not applicable):*
    N/A

4. Clinical cut-off:
    N/A

5. Expected values/Reference range:
    Channel 1 = 90 – 150 seconds; Channel 2 = > 999 seconds

N. Conclusion:

The submitted material in this premarket notification is complete and supports a substantial equivalence decision.